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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,815	07/19/2007	Makoto Suematsu	K2100.0002	9015

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EXAMINER	
YEAGER, RAYMOND P	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,815	SUEMATSU, MAKOTO	
	Examiner	Art Unit	
	Raymond P. Yeager	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,31,34-42 and 44-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25, 31, 34-42, and 44-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 to 25, 31, 34 to 42, and 44 to 49 are pending.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1)A product and a process specially adapted for the manufacture of said product; or

(2)A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 to 7 are drawn to *an ATP promoter and a pharmaceutical composition*.

Group II, claim(s) 8 to 9 and 35 to 38 are drawn to *a method of releasing ATP*.

Group III, claim(s) 10 to 16 are drawn to *an ATP inhibitor and a pharmaceutical composition*.

Group IV, claim(s) 17 to 18 are drawn to *a method of inhibiting ATP release*.

Group V, claim(s) 19 to 21 and 25 drawn to *erythrocytes with T-state hemoglobulin and a pharmaceutical composition*.

Group VI, claim(s) 22 to 24 and 34 are drawn to *erythrocytes with R-state hemoglobulin and a pharmaceutical composition*.

Group VII, claim(s) 34 is drawn to *a method of measuring ATP*.

Group VIII, claim(s) 39 to 40 are drawn to *a method of controlling ATP release*.

Group IX, claim(s) 41 to 42 are drawn to *a controller*.

Group X, claim(s) 44 to 47 are drawn to *a method for treating an ischemic disease*.

Group XI, claim(s) 48 to 49 are drawn to *a method for treating a vasodilatory disease*.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to forma single general inventive concept." Moreover, as stated in PCT rule 13.2, "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled

only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art"

3. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

No common technical feature is shared between groups I-XI. Groups I-IX share a common technical feature which is the same special technical feature as noted in group I. The special technical feature of Group I is the *control of ATP release from erythrocytes*. The *control of ATP release from erythrocytes* of claim 1 does not present a contribution over the prior art. As disclosed in Jagger et al, 2001 (*Am. J. Physiol. Heart. Circ. Physiol.*, vol. 280:H2833-2839; as presented by applicant in the 10/20/2006 IDS) the *control of ATP release from erythrocytes* of instant claim 1 is not novel. Jagger et al, 2001 teaches carbon dioxide increases the release of ATP from erythrocytes (page H2836). As such, Group I does not share a special technical feature with the instant claims of Group(s) II-XI. Thus, the nine, and essentially all eleven, groups do not share the *control of ATP release from erythrocytes* as a special technical feature As such, there is no common special technical feature shared by groups I-XI. Therefore, the claims are not so linked with the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-XI is lacking.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. The applicant must elect the following species:

- If applicant elects Group I, the following species elections are required:
  - One specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)*;
- If applicant elects Group II, the following species elections are required:
  - One specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)*;

- If applicant elects Group III, the following species elections are required:
    - One specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)*;
- If applicant elects Group IV, the following species elections are required:
    - One specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)*;
- If applicant elects Group V, the following species elections are required:
    - One specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)*;
- If applicant elects Group VI, the following species elections are required:
    - One specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)*;
- If applicant elects Group VII, no species elections are required:
- If applicant elects Group VIII, the following species elections are required:
    - One specific *substance that inhibits anion permeation function of band 3 protein to an adenosine-added erythrocyte suspension*;
- If applicant elects Group IX, the following species elections are required:
    - One specific *substance that inhibits anion permeation function of band 3 protein to an adenosine-added erythrocyte suspension*;
- If applicant elects Group X, the following species elections are required:
    - One specific *pathology*;
- If applicant elects Group X, the following species elections are required:
    - One specific *pathology*;

Specifically, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon Applicant's election of species, the result must provide a single chemical species and a single condition or disease to be treated or improved.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, one specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)* for group I, one specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)* for group II, one specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)* for group III, one specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)* for group IV, one specific *promoter (i.e. substance which stabilizes the hemoglobin T-state in erythrocytes)* for group V, one specific *inhibitor (i.e. substance which stabilizes the hemoglobin R-state in erythrocytes)* for group VI, no species required for group VII, one specific *substance that inhibits anion permeation function of band 3 protein to an adenosine-added erythrocyte suspension* for group VIII, one specific *substance that inhibits anion permeation function of band 3 protein to an adenosine-added erythrocyte suspension* for group IX, one specific *pathology* for group X, and one specific *pathology* for group XI, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim(s) 1 is generic for group I, claim(s) 8 is generic for group II, claim(s) 10 is generic for group III, claim(s) 17 is generic for group IV, claim(s) 19 is generic for group V, claim(s) 22 is generic for group VI, claim(s) 34 is generic for group VII, claim(s) 39 is generic for group VIII, claim(s) 41 is generic for group IX, no claim(s) are generic for Group X, and no claims are generic for Group XI.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical feature for the following reasons: As noted *supra*.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond P. Yeager whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Fri 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/Leon B Lankford/
Primary Examiner, Art Unit 1651